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Proposed Regulation Agency Background Document

Agency name	Board of Health Professions; Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 75-40
Regulation title	Regulations Governing Criteria for Certification of Dialysis Technicians
Action title	Initial regulations
Document preparation date	/03

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

Chapter 995 of the 2003 Acts of the Assembly amended the Code of Virginia to establish a definition and title protection for “dialysis care technicians” or “dialysis patient care technicians.” Legislation further requires the Board of Health Professions to approve in regulation organizations by which a person could be certified in order to use one of the restricted titles. Only those who hold one of those titles are authorized in the Drug Control Act to possess and administer drugs used in dialysis treatments.

Basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and

chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18 VAC 75-40-10 et seq. Regulations Governing is being promulgated under the legal authority of § 54.1-2400, stating the powers and duties of health regulatory boards and Chapter 27.01 of Title 54.1 of the Code of Virginia, which requires the Board to promulgate regulations establishing criteria for practice as a dialysis care technician.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title.

Chapter 27.01 was created by action of the 2003 General Assembly, effective July 1, 2003. The legislation may be accessed at: <http://leg1.state.va.us/cgi-bin/legp504.exe?031+ful+CHAP0995>.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the new regulation is to approve the organization or organizations that can certify candidates with the appropriate competency and technical proficiency to perform as dialysis technicians. The intent of the legislation and the regulation that implements mandated certification was to protect persons who are receiving hemodialysis. If the technician providing patient care is not adequately prepared and trained, as verified by nationally-recognized certification, the patient may be at considerable risk for infection or improper treatment. The credentials set out in this regulation would establish a level of minimal competency as evidenced by a qualifying examination and certification. To the extent rules implementing certification criteria for dialysis care technicians will improve the qualifications and abilities of persons who provide dialysis services to a population of persons whose health is fragile or compromised, the regulations are necessary for the protection of the health and safety of the public.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The proposed regulatory action is intended to implement certain provisions of Chapter 995 of the 2003 Acts of the Assembly, which requires the Board to approve a certifying body for dialysis care technicians. While Chapter 27.01 provides only title protection, rather than licensure, certification or registration by a health regulatory board, the Drug Control Act (Chapter 34 of Title 54.1) limits the administration of drugs used in dialysis treatment to those persons who hold the protected titles. Therefore, practically speaking, it will be necessary for any individual, who is not a licensed health care professional, who seeks employment in a dialysis care facility to hold the certification specified in regulations adopted by the Board of Health Professions.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

- 1) The primary advantage to the public is the assurance that dialysis technicians have minimal education and training as evidenced by national certification. Therefore, patients who enter a hemodialysis center will not have to wonder whether the technician has been adequately prepared to provide care. The only disadvantage to the public is that persons who have been employed as dialysis technicians prior to the effective date of the regulation will be deemed "certified", but that is a provision of the legislation and cannot be altered by regulation.
- 2) There are no advantages or disadvantages to the Commonwealth. Since this regulatory scheme offers only title-protection, there will be no ongoing regulatory or disciplinary costs.
- 3) There is no other pertinent information regarding this regulatory action.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>There are no cost to the state for implementation and enforcement of the proposed regulation. The one-time cost of promulgating the regulation, including</p>
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	mailings to interested parties and a public hearing, will fall within the budget of the Board of Health Professions, which receives its funding from licensee fees charged by health regulatory boards.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	Persons who are employed as dialysis care technicians or dialysis patient care technicians and the hemodialysis centers in which they work.
Agency’s best estimate of the number of such entities that will be affected	As of November 3, 2003, there are 118 dialysis centers in Virginia. The number of dialysis technicians working in each varies from 1 to 30 working in varying capacities (equipment maintenance, patient care, etc.)
Projected cost of the regulation for affected individuals, businesses, or other entities	Cost for the certification examination by a national body recognized by the Board will range from \$125 for the CCHT to \$195 for the CHT or the CCNT. Recertification is required with a renewal fee of \$50 every two years for the CCHT, \$55 every year for the CHT, and reexamination every four years at a cost of \$195 for the CCNT. There will be no additional cost for the centers unless they choose to assist their employees with certification.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The most frequent comment from representatives of certifying organizations, dialysis technicians and patients who wrote or spoke with the Board during public comment at meetings was an objection to a rule that would allow currently practicing technicians to continue to practice indefinitely without certification. While the Board understood the rationale for their objections, it was explained that the 2nd enactment clause of HB2605 provides that persons who have completed a training program in accordance with the Core Curriculum for Dialysis Technicians or a comparable educational program are authorized to continue employment and administration of medications and are deemed to be certified. Since those persons are “grandfathered” under the law, regulations of the Board cannot require a different qualification.

The Board also considered the alternative of certifying programs and examinations according to standards established in regulation. The Director of the Renal Division of Riverside Health System wrote about their classroom and clinical program for renal dialysis technicians and requested

consideration of Board certification for the program and examination. The Board looked at models for state certification such as those in California, New Mexico and Arizona, where there are state fees for certification and renewal and educational program are approved by a governmental entity such as the board of nursing. After much consideration about the advantages and disadvantages of certifying programs, the Board concluded that: 1) there is no statutory authority for such a regulatory scheme, as the law requires a person to have certification from an organization approved by the Board rather than to have certification from the Board based on an educational program and examination approved by the Board; 2) there are no resources, either staffing or financial, to perform the tasks and cover the cost required for review, approval and monitoring of educational programs and examinations as would be necessary to ensure quality and consistency; and 3) there is no necessity for Board certification since there are several nationally-recognized bodies currently offering certification to applicants who are graduates of educational and training programs in Virginia. After examining all alternatives, the Board decided that the least burdensome regulation was to recognize national certification by bodies that have established credibility in the renal dialysis profession and have psychometrically-proven examinations.

In examining all the certifying bodies and credentials, the Board considered factors such as recognition by other states, endorsements from professional groups in the dialysis field, impartial validation of the certifying examination, accessibility and cost, and applicability of certification to patient care. The following comparative chart was used as a decision matrix for the regulation:

Comparison of Hemodialysis Technician Certification

Examination	Certified Clinical Hemodialysis Technician	Certified Hemodialysis Technician	Certified Nephrology Technology	Biomedical Nephrology Technology
Credentials	CCHT	CHT	CCNT	CBNT
Level of measurement	Initial competency	Technical proficiency	Advanced	Advanced
Certification Organization	Nephrology Nursing Certification Commission (NNCC)	Board of Nephrology Examiners, Inc. Nursing and Technology (BONENT)	National Nephrology Certification Organization (NNCO)	National Nephrology Certification Organization (NNCO)
Testing Agency	Center for Nursing Education and Testing (C-NET)	Applied Measurement Professionals, Inc. (AMP)	Professional Testing Corporation (PTC)	Professional Testing Corporation (PTC)
Eligibility Requirements	<ol style="list-style-type: none"> 1. Possess a minimum of a high school diploma or its equivalent (GED). 2. Have successfully completed a training program for hemodialysis patient care technicians that included both classroom instruction and 	<ol style="list-style-type: none"> 1. High school diploma or equivalent. 2. One year of experience (12 mos.) in nephrology patient care, current active participation in an ESRD facility or successful completion of an accredited dialysis course approved by 	<ol style="list-style-type: none"> 1. High school diploma or the equivalent. 2. At least one year full-time or the equivalent (2,000 hours) experience in nephrology technology or completion of at least a one-year educational 	<ol style="list-style-type: none"> 1. A minimum of a high school diploma or the equivalent. 2. At least one year full-time or the equivalent (2,000 hours) experience in nephrology technology or completion of at least a one-year educational

	<p>supervised clinical experience.</p> <p>3. Obtain the signature of a supervisor to verify training and clinical experience. It is recommended, but not required, that an applicant have a minimum of six months (or 1,000 hours) of clinical experience, including the training period, prior to taking the exam.</p> <p>4. Be in compliance with state regulations of the practice of hemodialysis patient-care technicians. Applicants must meet the experience requirement (for certification) of the state in which the practice.</p>	<p>the BONENT Board.</p> <p>3. Applicants will be required to submit two letters of reference with their applications.</p> <p>4. Applicants must complete the application in its entirety and sign.</p>	<p>program in nephrology technology.</p> <p>3. Completion and filing of an Application for the Certification Examinations in Nephrology Technology.</p> <p>4. Payment of required fee.</p>	<p>program in nephrology technology.</p> <p>3. Completion and filing of an Application for Certification Examinations in Nephrology Technology.</p> <p>4. Payment of required fee.</p>								
Content	<p>Dialysis Practice</p> <table border="0"> <tr> <td>Clinical</td> <td>50%</td> </tr> <tr> <td>Technical</td> <td>23%</td> </tr> <tr> <td>Environment</td> <td>15%</td> </tr> <tr> <td>Role</td> <td>12%</td> </tr> </table>	Clinical	50%	Technical	23%	Environment	15%	Role	12%	<p>Patient care 65%</p> <p>Machine technology 10%</p> <p>Water treatment 5%</p> <p>Dialysis Reprocessing 5%</p>	<p>Principles of dialysis 25%</p> <p>Machine preparation & Operation 20%</p> <p>Patient assessment 20%</p> <p>Treatment 35%</p>	<p>Principles of dialysis 25%</p> <p>Scientific concepts 15%</p> <p>Electronic applications 10%</p> <p>Water treatment 20%</p> <p>Equipment functions 20%</p> <p>Environmental/regul. Issues</p>
Clinical	50%											
Technical	23%											
Environment	15%											
Role	12%											
Recertification Required	<p>Every two years</p> <p>Renewal Fee: \$50.00</p> <p>20 Contact Hours & 2000 Hours of Work</p> <p>Experience</p>	<p>Every four years</p> <p>Annual renewal fee: \$55.00</p> <p>45 Contact Hours</p>	<p>Every four years</p> <p>Re-examination: NANT members/\$195.00</p> <p>Non-members/\$250.00</p>	<p>Every four years</p> <p>Re-examination: NANT members/\$195.00</p> <p>Non-members/\$250.00</p>								
Cost	\$125.00	\$195.00	\$195.00 / \$250.00	\$195.00 / \$250.00								
Endorsement	<p>Nat. Assoc. of Nephrology Technicians/ Technologists (NANT)</p> <p>American Nephrology Nurses' Association (ANNA)</p>	(NANT)	(NANT)	(NANT)								

Of the certifying bodies reviewed, the CCHT offered by the Nephrology Nursing Certification Commission appears to be the least expensive and most appropriate for testing minimal competency. However, there are technicians in Virginia and in other states who have already obtained the CHT from BONENT or the CCNT from the NNCO. It is certainly logical to recognize a certification that demonstrates greater technical proficiency or an advanced level of knowledge and training in addition to the certification at an entry level. The Board considered the CBNT (Biomedical Nephrology Technology) but concluded that it is designed for persons who have responsibility for the dialysis equipment and is not an appropriate certification for persons with responsibilities for patient care, so it was not included in the regulation.

Another issue that was addressed during development of regulations was the ability of candidates for certification to obtain clinical experience prior to sitting for the examination. It would appear that a sufficient amount of clinical experience will be gained through the training program to allow a person to sit for the certification examination. While the BONENT examination specifies one year of experience, representatives of that group have told the Board that clinical experience gained in a training program and in non-patient care functions in a dialysis center may be counted to allow someone to sit for the examination.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

A Notice of Intended Regulatory Action was published in the Register of Regulations and posted on the Townhall on July 14, 2003 with public comment accepted through August 13, 2003. The following public comment was received:

The Director of Clinical and Regulatory Services for American Renal Associates wrote in support of a standardized training program and competency test for dialysis technicians. In Ohio, the BONENT certification is required, but she pointed out that the BONENT exam requires one year of experience in dialysis care as a prerequisite. Their company will reimburse the technician if he/she passes the exam.

The Legislative Affairs Director of the National Association of Nephrology Technicians/Technologists (NANT) supports a certification test to validate the individual's knowledge base. NANT supports continuing education for dialysis technicians and opposes a "grandfather" clause that allows technicians to avoid certification. It would support allowing an extended time for those persons to comply with the law.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
n/a	10	n/a	Section 10 sets out the definitions for terms used in these regulations, including the protected titles of “dialysis patient care technician” and “dialysis care technician.” The definitions are identical to those found in § 54.1-2729.2.
n/a	20	n/a	<p>Section 20 delineates the scope of practice for dialysis care technicians including requirements for certification of any technician who provides direct patient care in a Medicare-certified renal dialysis facility and who administers certain medications necessary for dialysis treatment. Practice of dialysis care technicians must only occur under the direction of a licensed practitioner of medicine or a registered nurse and administration of medications can only occur under the direct and immediate supervision of a registered nurse. This section also sets out those duties that may be performed by a person who does not hold certification to include activities relating to the technical elements of dialysis, such as equipment maintenance.</p> <p>The scope and limitations on practice, including the specific requirements for supervision are set forth in §§ 54.1-2729.1, 54.1-2729.2 and 54.1-3408 (O).</p>
n/a	30	n/a	<p>Section 30 establishes the criteria for use of the protected titles. The Board has approved certification from three organizations that examine candidates for appropriate competency and technical proficiency. The three credentials that are approved are:</p> <ol style="list-style-type: none"> 1. Certified Clinical Hemodialysis Technician (CCHT) by the Nephrology Nursing Certification Commission (NNCC); 2. Certified Hemodialysis Technician (CHT) by the Board of Nephrology Examiners Nursing and Technology (BONENT); and 3. Certified in Clinical Nephrology Technology (CCNT) by the

			<p>National Nephrology Certification Organization (NNCO).</p> <p>In addition, the Board will recognize certification or licensure as a dialysis technician or similar title by another jurisdiction in the United States provided the standards for certification or licensure or substantially equivalent to those in Virginia.</p> <p>The credentialing bodies recognized by the Board are all national in scope, require education and practical experience in dialysis care, offer a psychometrically tested examination, and test for competency and technical proficiency in providing patient care functions in a renal dialysis facility. The Board also chose to recognize certification or licensure from another state provided it is based on substantially equivalent criteria, such as education and training and passage of an examination.</p>
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